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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/350,393	07/09/1999	RAY J. WU	19603/2760(C	7999

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EXAMINER	
COLLINS, CYNTHIA E	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/350,393	WU ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-17 and 37-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-10, 12-14, 16-17 and 37* is/are rejected.

7)☒ Claim(s) *11, 15 and 38-47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed November 22, 2004 has been entered.

Claims 5 and 18-36 are cancelled.

Claim 1 is currently amended.

Claims 38-47 are newly added.

Claims 1-4, 6-17 and 37-47 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 1-10, 12-14, 16-17 and 37 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed May 19, 2004.

Applicant's arguments filed November 22, 2004 have been fully considered but they are not persuasive.

Applicants assert that the grounds for rejection lack merit. Applicants maintain that contrary to the assertion that the specification does not describe transforming the plants with expression cassettes comprising other abscisic acid response complex units of different structure

obtained from other sources, or other minimal promoters of different structure obtained from other sources that have been truncated, or other Hva22 introns, the specification does describe abscisic acid response complex (ABRC) units from the barely HVA22 gene, and from the barley HVA1 gene. Applicants also maintain that, given the skill and knowledge in the art with respect to ABRC units, the skilled artisan would readily understand the common attributes associated with ABRC units and that the two disclosed ABRC units are thus sufficient representative of a genus of ABRC units. (reply pages 6-7)

The Examiner maintains that the description of only two different ABRCs obtained from a single plant species coupled with the exemplification of one of these ABRCs in a construct is not sufficiently representative of the genus of ABRC units recited in the claims, i.e. ABRC units that have an unspecified structure and that may be obtained from any source and that, when operably linked in any configuration with a minimal promoter and a DNA molecule that increases tolerance to salt stress and drought stress in plants, function to express the DNA molecule and confer tolerance to salt stress and drought stress in monocotyledonous plants transformed therewith.

Regarding the minimal promoter element, Applicants point out that claim 1 has been amended to further limit the minimal promoter element to those recited in claim 5 (now canceled). In particular, claim 1 now recites minimal promoters that were identified in the specification at page 12, lines 3-6. Further, because the truncated promoters must retain their function (as recited in the claims), and because the recited truncated promoters are well known in the art, Applicants maintain that the skilled artisan art would reasonably conclude that they were

in possession of the claimed invention. Applicants point out, for example, that one of ordinary skill in the art would understand that in order to function as a promoter, the truncated version must include such essential elements as a TATA box (or the like), and that the teaching in the art identifies specific minimal or truncated promoters such as those claimed.

In this regard Applicants point in particular to the Act1-100 minimal promoter which is described and shown to be active in Examples 15-31 of the specification and which corresponds to Su J. et al. (Dehydration-stress-regulated transgene expression in stably transformed rice plants. Plant Physiol. 1998 Jul;117(3):913-22, Applicant's IDS and attached hereto as Exhibit A). Applicants also point in particular to Lu C. et al. (Three novel MYB proteins with one DNA binding repeat mediate sugar and hormone regulation of alpha-amylase gene expression. Plant Cell. 2002 Aug;14(8):1963-80, attached hereto as Exhibit B), where a truncated α-amylase promoter of barley was described and shown to be active. Applicants additionally point in particular to Odell J. et al. (Identification of DNA sequences required for activity of the cauliflower mosaic virus 35S promoter. Nature. 1985 Feb 28-Mar 6;313(6005):810-2, attached hereto as Exhibit C) in which a truncated CaMV 35S promoter has been identified and shown to be active. Applicants maintain that in view of the description of minimal promoters in the specification, as well as the level of knowledge in the art of the recited truncated promoters, one of skill in the art would reasonably conclude that applicants were in possession of the recited truncated promoters at the time of fling. (reply pages 7-8)

The Examiner maintains that while the specification at page 12 makes reference to "Act1-100 of rice, a shortened α-amylase promoter of barley or rice, a shortened maize ubiquitin promoter, or a shortened CaMV promoter" as being suitable minimal promoters, the

specification at page 12 does not describe the structure of these promoters, or refer to any source or publication that describes these promoters. That one of ordinary skill in the art would generally understand that in order to function as a promoter, the truncated version must include such essential elements as a TATA box (or the like), such a general understanding does not describe the nature and extent to which any particular promoter, such as α-amylase promoter of barley or rice, the maize ubiquitin promoter or the CaMV promoter, may be shortened and still function within the context of the claimed invention.

With respect to the cited reference of Su et al., the Examiner has previously acknowledged the description of the Act1-100 minimal promoter of rice disclosed and exemplified in the specification (for example at page 5 of the office action mailed May 19, 2004). With respect to the cited reference of Lu C. et al., the Examiner maintains that the single species of a truncated barley α-amylase promoter used by Lu C. et al. and disclosed in the pre-filing date publication of Gomez-Cadenas A. et al. (An abscisic acid-induced protein kinase, PKABA1, mediates abscisic acid-suppressed gene expression in barley aleurone layers. Proc Natl Acad Sci U S A. 1999 Feb 16;96(4):1767-72) is not sufficiently representative of the genus of truncated barley α-amylase promoters recited in the claims, the nature and extent of whose truncations is not specified, which promoters, when operably linked in any configuration with one or more unspecified ABRCs and a DNA molecule that increases tolerance to salt stress and drought stress in plants, function to express the DNA molecule and confer tolerance to salt stress and drought stress in monocotyledonous plants transformed therewith. With respect to the cited reference of Odell J. et al., the Examiner maintains that the four species of a truncated CaMV 35S promoter that can drive the transcription of human growth hormone (hgh) in tobacco cells

and plants is not sufficiently representative of the genus of truncated CaMV 35S promoters recited in the claims, the nature and extent of whose truncations is not specified, which promoters when operably linked when operably linked in any configuration with one or more unspecified ABRCs and a DNA molecule that increases tolerance to salt stress and drought stress in plants, function to express the DNA molecule and confer tolerance to salt stress and drought stress in monocotyledonous plants transformed therewith.

Regarding the assertion that the specification does not describe expression cassettes comprising the recited components operably linked in other configurations, or operably linked to permit expression of the DNA molecule in leaves or root of the plant, Applicants submit that this mound for rejection has been obviated by amending claim 1 to delete the phrase "in leaves or roots of the plant.". Regarding the assertion that the specification does not disclose a representative number of species of expression cassettes to support the claimed genus of expression cassettes whose components are operably linked to both permit expression of a DNA molecule in leaves or root of the plant and confer tolerance to salt stress and drought stress in the plant upon expression of said DNA molecule, nor the structural features unique to the genus, Applicants submit that this ground also has been obviated by the amendments to claim 1. (reply pages 7-8)

The amendment of claim 1 to eliminate reference to expression in leaves or roots and to recite particular subgenera of minimal promoters does not obviate the rejection because the claims are still directed to the use of a broad genus of expression cassettes comprising

subcombinations (any unspecified combination of at least one ABRC, a minimal promoter, a DNA molecule, and an Hva22 intron) that are not adequately described.

Claims 1-10, 12-14, 16-17 and 37 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for conferring tolerance to salt stress and drought stress in a monocotyledonous plant comprising transforming the monocotyledonous plant with the exemplified expression cassettes contained in plasmids pJS112, pJP21, and pJPM001, does not reasonably provide enablement for other methods that require transforming monocotyledonous plants with other expression cassettes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed May 19, 2004.

Applicant's arguments filed November 22, 2004 have been fully considered but they are not persuasive.

Applicants maintain that the basic techniques used to construct expression cassettes are well known in the art, and that the specification provides adequate disclosure to enable one of ordinary skill in the art to prepare the expression cassette recited in claim 1. Applicants point out that, in particular, the specification identifies the three key components that must be included in the expression cassette of the present invention, and that the plasmids identified by the USPTO are working examples of how to make the expression cassette with an Actl-100 promoter. Applicants maintain that based on this teaching, one of ordinary skill in the art would be able to

make, without undue experimentation, expression cassettes with the other recited minimal promoters. (reply page 8)

The Examiner maintains that the outstanding scope of enablement rejection was not predicated on a failure to provide guidance with respect to the basic techniques used to construct expression cassettes, which would have been within the abilities of one skilled in the art at the time of filing. The outstanding scope of enablement rejection was predicated on the unpredictability of the claimed polynucleotide components permitting expression of a DNA molecule in a manner that confers tolerance to salt stress and drought stress, and on a failure to provide guidance with respect to how to combine the claimed polynucleotide components to permit expression of a DNA molecule in a manner that confers tolerance to salt stress and drought stress (pages 8-10 of the office action mailed May 19, 2004).

Applicants further maintain that their position is supported by Lee J. et al. (Expression of *Arabidopsis* CBFI Regulated by an ABA/stress Inducible Promoter in Transgenic Tomato Confers Stress Tolerance Without Affecting Yield, Plant Cell Environ 26:1181-1190, 2003), attached hereto as Exhibit D. Applicants point out that Lee J. et al. transformed tomato plants with the CRT/DRE binding factor 1 (CBF1) gene of *Arabidopsis thaliana*, which had previously been shown to improve tolerance to cold, drought, and salt loading in tomatoes using a strong constitutive CaMV 355 promoter, with the transgenic plants produced by this method having decreased yield under normal growth conditions. Applicants also point out that Lee J. et al. transformed tomato using an expression cassette including an ABRC unit from the barley HAV22 gene linked to a truncated α-amylase promoter of barley (i.e., amy64) to drive

expression of the *Arabidopsis* CBF1 gene, with the transgenic plants produced by this method having enhanced tolerance to chilling, water-deficit, and salt stress, without sacrificing yield. Applicants further point out that Lee J. et al. describe using the techniques of Su J. et al. (Dehydration-stress-regulated transgene expression in stably transformed rice plants. Plant Physiol. 1998 Jul;117(3):913-22, Applicant's IDS and attached hereto as Exhibit A) for constructing the expression cassette, Su J. et al. being co-authored by the co-inventors of the present invention and included in the specification as Examples 15-31. Applicants maintain that in view of the foregoing remarks and the amendments to claim 1, the rejection for lack of enablement is improper and should be withdrawn. (reply pages 8-9)

The Examiner reiterates that the outstanding scope of enablement rejection was not predicated on a failure to provide guidance with respect to the basic techniques used to construct expression cassettes, which would have been within the abilities of one skilled in the art at the time of filing. The outstanding scope of enablement rejection was predicated on the unpredictability of the claimed polynucleotide components permitting expression of a DNA molecule in a manner that confers tolerance to salt stress and drought stress, and on a failure to provide guidance with respect to how to combine the claimed polynucleotide components to permit expression of a DNA molecule in a manner that confers tolerance to salt stress and drought stress (pages 8-10 of the office action mailed May 19, 2004).

With respect to the cited references, Su J. et al., whose techniques were relied upon by Lee J. et al., the Examiner maintains that Su J. et al. only provides guidance for making and using constructs that comprise the ABA-response complex (ABRC1) from the barley HVA22 gene fused to the 5' region from the rice (*Oryza sativa* L.) Act1 gene for the expression of a GUS

reporter gene in barley aleurone cells. Su J. et al. do not provide guidance for making the full scope of claimed constructs which include constructs that comprise at least one abscisic acid response complex unit of undefined structure obtained from any source and a minimal promoter of undefined structure obtained from the α-amylase gene promoter of barley or rice, the ubiquitin gene promoter of maize, or the CaMV 35 S promoter, operably linked together in an unspecified manner with any DNA molecule that increases tolerance to salt stress and drought stress in plants, and further comprising at an unspecified location an Hva22 intron of undefined structure, which constructs confer tolerance to salt stress and drought stress in monocotyledonous plants transformed therewith.

Allowable Subject Matter

Claims 11, 15 and 38-47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Examiner
Art Unit 1638

CC

Cynthia Collins 2/2/05